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Arrhythmias

FIDELIS IMPLANTABLE DEFIBRILLATOR LEAD PERFORMANCE IN CHILDREN: DATA FROM THE INTERNATIONAL PEDIATRIC LEAD EXTRACTABILITY AND SURVIVAL EVALUATION (PLEASE) STUDY

Poster Contributions
Poster Sessions, Expo North
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Background: Implantable cardioverter-defibrillator (ICD) therapy in children and congenital heart disease (CHD) patients is hindered by poor long-term lead survival. Distinct lead design changes including thinner diameter leads were introduced in order to improve extractability; however, a subset of these leads was recalled due to high failure rates.

Methods: We examined the outcomes of the recalled Sprint Fidelis® leads in pediatric and CHD patients as a sub-analysis within the Pediatric Lead Extractability and Survival Evaluation (PLEASE) study, an international registry involving 24 centers. Pediatric and CHD patients who underwent ICD lead implants from 2005-2010 were eligible.

Results: Study subjects comprised 878 young ICD patients (44% CHD). Mean±SD age at implant was 18.6±9.8 years. Of the 965 total ICD leads, 54% were Thin (≤ 7Fr) with 300 (58%) being Fidelis® leads. There was a total of 139 (14%) failed leads in 132 (15%) patients at mean lead age of 2.0±1.4 years. Of the Fidelis® leads, 33% (98/300) failed, accounting for 71% (98/139) of all failed leads and 85% (98/115) of all failed thin leads. For the 4 Fidelis® models (6930, 6931, 6948 and 6949) the number of failed leads was 0/1, 57/138 (41%), 3/16 (19%), and 38/145 (26%), respectively. Of the failed single coil leads, 72% (57/79) were Fidelis®model 6931. The majority (44%) of failed Fidelis® leads were associated with inappropriate shocks. The actuarial yearly failure rate was 9.1% for Fidelis® leads compared to 2.1% for non-thin leads.

Conclusions: Fidelis® leads accounted for the majority of ICD lead failures and associated inappropriate shocks during the study period. The annual failure rate is several-fold higher compared to non-thin leads as well as published Fidelis® annual failure rates in adult cohorts. The steady and high annual failure rate represents an ongoing burden for these young patients. Although children may have potentially benefitted from a thinner ICD lead, unfortunately they have been disproportionately impacted by this specific lead failure and recall. More robust ICD lead designs are critical for the long-term well-being of pediatric device patients. Clinical Trial Registration: NCT00335036